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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,285	03/23/2001	Hitoshi Nomura	12660-002001	1001

7590 10/19/2004

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,285	NOMURA ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-50* is/are pending in the application.

4a) Of the above claim(s) *29,30,33,35,36,41,42,48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-28,31-34,37-40,43-47,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-50* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/01, 12/02, 1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I, drawn to human NR8 in the reply filed on 6/26/2004 is acknowledged. Applicants have pointed out that claims 26, 43, 45 and 46 should have been included in Group II. It is noted that several claims fell within both groups I and II.

Claims 28-30, 35, 36, 41, 42, 48 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/26/2004.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are under consideration as they are drawn to the elected invention.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.
Note that applicant's work address may not be substituted for the residence address.

Claim Objections

Claims 22, 23, 37, 38, 44, 47 and 50 are objected to for reading on a non-elected invention, murine NR8. Applicants are required to amend the claims to limit them to the elected invention.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The drawings are objected to because the copy quality is not sufficient for printing, especially (but not limited to) those drawings which are reproductions of photographs. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. This application claims priority to Japanese applications 10/214720 and 10/297409. The certified copies are present in the file. No English language translations have been provided. Accordingly, priority is set at the filing date of the PCT application, 6/23/1999.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that refer to the protein claimed or encoded by the claimed nucleic acids only as 'hemopoietin receptor NR8" (as in claim 22) or "NR8 alpha, beta, or gamma" are indefinite for failing to adequately point out that which applicant sees as the invention. Mere recitation of a name is insufficient to identify the claimed subject matter. The specification as filed discloses three distinct species of protein which are designated NR8 alpha, beta, or gamma. However, there is no description of the identifying features of such, including conserved structure or function. Accordingly, the person of ordinary skill in the art would not be able to determine the metes and bounds of the recitations 'hemopoietin receptor NR8" (as in claim 22) or "NR8 alpha, beta, or gamma" (as in claim 23). Further, different parties may identify the same protein by different names. For example, the protein identified by applicants as NR8 has been identified in the art by numerous other names including (but not limited to) Z alpha 11 ligand polypeptide, orphan cytokine receptor 10-A, IL-9/IL-2 receptor-like 16445 protein, and MU-1 hematopoietic receptor protein. Accordingly, mere recitation of a name is not sufficient to identify the subject matter for which patent protection is sought.

Claims which recite "a modified"..."polypeptide with one or more amino acids deleted, added or substituted with a different amino acid, and being functionally equivalent to...", such as claims 24-25 and 27-28, are indefinite because there is no upper limit on the deletions, additions or substitutions, such that there is no requirement for structural conservation and thus the metes and bounds of the claims cannot be determined. Further, as no function has been disclosed for the various disclosed NR8 proteins, nor any functions that would serve to distinguish NR8-alpha from -beta from -gamma, the person of ordinary skill in the art would not

be able to determine if a given protein were or were not "functionally equivalent" to one of the disclosed proteins.

Claims that recite that a nucleic acid "hybridizes" to another nucleic acid, such as claim 31, are indefinite the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. Hence, without specification of hybridization conditions, the metes and bounds of the claims cannot be determined. Claim 50, which recites "specifically hybridizing" is similarly indefinite. The mere recitation that hybridization is 'specific' does not serve to define the metes and bounds of the claim.

Claim 45 is indefinite for failing to specify the interrelationship between the recited elements. Further, as written, claim 45 fails to further limit claim 43, as all cells comprise "expression regulating nucleotide sequences", such that any cell comprising the nucleic acid of claim 43 would meet the limitations of claim 45.

Claim 46 is an incomplete method claim, as insufficient elements are recited to result in the production of the recited "NR8 polypeptide".

Claim Rejections - 35 USC § 101 and §112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The specification presents a set of related sequences, which are purported to be a putative hematopoietic cytokine receptor, designated NR8 by applicants. However, it is clear from the specification that at the time the invention was made, the inventors had not attributed any specific activity to the protein, nor correlated the presence or absence of such, or nucleic acids encoding it, with any specific condition. The specification proposes as utilities for the claimed subject matter that it "might" be a receptor for an unknown hematopoietic factor (page 8), that "it

is possible that NR8 is specifically expressed in limited cell populations" and could be therefore used for cell sorting (page 8), and that it is useful in screening for a ligand or other compound that binds to NR8 (page 9).

Although the assertion that NR8 is a hematopoietic cytokine receptor is specific, it was not a substantial assertion at the time the invention was made, but rather an invitation to experiment to determine what kind of receptor it was, what ligand it bound, what the resultant activity was, etc. In the absence of all such information, there was no readily available utility for the claimed subject matter at the time the invention was made, based upon the information in the specification as filed. Hematopoietic cytokines have different functions, and act on different cells at different times, to different effect; the varied effects may include stimulation of growth, proliferation, differentiation, or even apoptosis (cell killing). Further, the same cytokine may have different effects under different conditions, or on different cell types. Without any knowledge of what type of cell carries the receptor protein and what the biological effect of binding is, the person of ordinary skill in the art would not know how to use the claimed invention, but would have to experiment to determine these properties and thus a use that would be dependent on or take advantage of such. Such experimentation to determine a utility is considered to be part of the inventive process.

Utility must be in readily available form. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide and protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as NR8 protein or the polynucleotides encoding it, the claimed invention is incomplete. Merely using the

polynucleotides to isolate other similar polynucleotides, or using the protein to find things that bind it, does not constitute a patentable utility.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a putative receptor designated NR8, and all functional equivalents thereof. Also claimed are nucleic acids encoding such and nucleic acids that hybridize to such, as well as uses for both the protein and the nucleic acids. The specification discloses no function of the protein. Only a limited number of nucleic acid sequences are disclosed, specifically a single human and a single mouse sequence, with three splice variants of each. There is no disclosure of any other derivatives. Given the lack of any specific function, there is clearly no specific conception of any functionally equivalent derivative or analog, nor any such functional equivalent that might be encoded by a nucleic acid that would hybridize to any of the disclosed nucleic acids. The limited disclosure of two nucleic acid sequences is not sufficient to support the scope of claims to all possible functional equivalents; the written description does not provide sufficient guidance to such, nor does it present any information that would lead one to conclude that applicants had conceived of or had possession of such species.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides or proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the nucleic acids and proteins of SEQ ID NO: 1-8 and 14-18, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections over Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Donaldson et al., U.S. Patent Number 6,057,128.

Donaldson et al. disclose and claim MU-1 cytokine receptor, nucleic acids encoding such, host cells, and vectors. Fragments and fusion proteins are disclosed at column 3. SEQ ID NO: 2 of Donaldson is 100% identical to SEQ ID NO: 7 of this application, and Donaldson's nucleic acid sequence, SEQ ID NO: 1 is 100% identical in the coding region to SEQ ID NO: 8. Accordingly, the claims are anticipated by the disclosure of Donaldson et al.

Claims 22-28, 31-34, 37-40, 43-47, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Presnell et al., U.S. Patent Number 6,576,744. The Presnell patent merits priority to 9/23/1998

Presnell et al. disclose and claim cytokine receptor zAlpha11, having residues 20-237, 20-255, or 20-538 (among others) of a sequence corresponding to SEQ ID NO: 7 of this application, which corresponds to the β and γ forms. Nucleic acids encoding such, host cells, vectors and recombinant production are also disclosed, see for example columns 1-3. Accordingly, the claims are anticipated by the disclosure of Presnell et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Parrish-Novak et al., Nature 408:57-63, cited by applicants, is cited as evidence of the type of experimentation required to establish utility for the IL-21 receptor. The paper discloses that IL-21 and its receptor are involved in natural killer cell expansion and regulation of lymphocyte function. NR8 is the same as IL-21 receptor.

Mehta et al., J. Immunology170 :4111-4118, 2003, disclose that IL-21 induces the apoptosis (killing) of resting and activated primary B cells.

Thus, the art has established that IL-21 is capable of stimulating expansion of some cells, and killing others.

Conclusion

No claim is allowed.

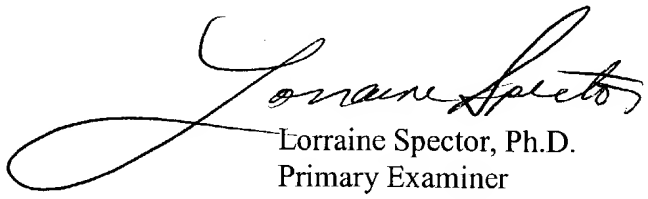
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner

10/18/04